UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **THIS DOCUMENT RELATES TO:** *Track One Cases*	)	**MDL 2804** **Case No. 1:17-md-2804** **Judge Dan Aaron Polster** **OPINION AND ORDER GRANTING IN PART AND DENYING IN PART MOTION TO EXCLUDE KESSLER AND PERRI**

Before the Court is Defendants' Motion to Exclude the Testimony of David A. Kessler, M.D. and Mathew Perri, III BS Pharm, Ph.D., RPh. ("Kessler/Perri Motion") **(Doc. #: 1927)**. The Court has carefully considered the Kessler/Perri Motion, Plaintiffs' Response **(Doc. #: 2195)**, and Defendants' Reply **(Doc. #: 2536)** and **GRANTS IN PART AND DENIES IN PART** the Kessler/Perri Motion.

I. Legal Standards.

The Court incorporates the general legal standards set forth in the Court's Opinion and Order regarding Defendants' motion to exclude the opinion and testimony of Prof. Meredith Rosenthal. *See* Doc. #: 2495.

II. Introduction.

Plaintiffs intend to call Kessler to testify about the United States Food and Drug

Administration's ("FDA") regulatory scheme, FDA practice and procedure, the FDA's relationship with pharmaceutical companies, the standard of care applicable to the pharmaceutical industry based on Kessler's training and experience, the Manufacturers' compliance with FDA regulations and industry standards, and the impact of the Manufacturers' compliance or lack thereof. *See* Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude the Testimony of David Kessler, M.D. and Matthew Perri ("Pls. Opp. Resp. re Kessler & Perri") at 23 (Doc. #: 2195).

Perri was retained by Plaintiffs to explain pharmaceutical marketing, how it differs from other marketing, and the marketing standards prescription opioid marketers should follow. *See id.* at 3. Perri opines about Defendants' prescription opioid marketing strategies and messages, how these strategies were implemented and messages disseminated, and the effectiveness of both. *Id.*

Defendants seek to exclude both experts' testimony to the extent it constitutes a narrative or presents opinions about Manufacturer knowledge, intent, or state of mind. Defendants further seek to exclude Perri's testimony, in its entirety, arguing his methodology is not reliable and his opinions are not relevant. Defendants also move to exclude Kessler's opinions on the additional grounds that they contain legal conclusions and, as to Noramco and Tasmanian Alkaloids, are untimely.

For the reasons set forth below, the Court grants in part and denies in part the Kessler/Perri Motion.

III. Kessler.

A. Credentials and Experience.

Kessler received his J.D. from the University of Chicago in 1978 and his M.D. from

Harvard University in 1979. *See* Expert Report of David Kessler, M.D. ("Kessler Report") at 10 (Doc. #: 1927-3). In 1990, Kessler was appointed as Commissioner of the FDA, where he served until 1997. *Id.* In his role as FDA Commissioner, Kessler was responsible for implementing and enforcing the United States Food, Drug, and Cosmetic Act. Among his responsibilities, Kessler oversaw the Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and Center for Biologics[1] Evaluation and Research. *Id*. He created the Office of Criminal Investigations and was responsible for the FDA's Division of Drug Marketing, Advertising, and Communications. *Id.* at 11. Kessler also served as Dean of the Yale University School of Medicine and Dean of the School of Medicine at the University of California, San Francisco. *Id*. at App'x. 1 at 1.

During his career, Kessler has been awarded numerous honors, has served on several boards of directors, and has published articles in legal, medical, and scientific journals on a variety of topics, including the federal regulation of food, drugs, and medical devices, drug promotion and marketing practices, and addiction. *See* Pls. Opp. Resp. re Kessler & Perri at 2 (Doc. #: 2195).

B. Opinions.

Plaintiffs retained Kessler to offer opinions concerning: the Food Drug & Cosmetics Act, 21 U.S.C. § 301, *et seq*. ("FDCA"); legal standards, regulation, guidance, and industry practice pertaining to the sponsors of prescription opioids; and whether documents produced in discovery establish that the Manufacturers "departed from accepted regulatory standards" and, if so, how.

[1] "Biologics" are a biological products used in medicine such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. *See* https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

Kessler Report at 13 (Doc. #: 1927-3). In addition, Kessler offers marketing causation opinions, ultimately concluding that:

> the manufacturers' departures from FDA standards would be expected to (and likely did) have an affect on how healthcare providers prescribed opioids, contributing to a shift in the practice of medicine with regards to the use of opioids in the treatment of pain. This change in the practice of medicine led to an increase in opioid prescriptions, an increase of opioids in interstate commerce, and an increase in inappropriate use of opioids, all of which in turn increased the risk of opioid abuse and contributed to a public health crisis.

Id. at 320.

Kessler's report first addresses the responsibilities of manufacturers pursuant to the FDCA. *See Id*. at 14-25. He then offers specific opinions about how the marketing and promotional activities of various Manufacturers deviated from their FDA responsibilities which, in turn, increased the risk of opioid abuse and endangered patient safety. *Id*. at 31-291. Kessler also opines that the Manufacturers' support for, and involvement with, pain advocacy groups, professional medical groups, and trade groups worked to expand opioid use and increased the risk of opioid abuse. *Id*. at 295-313.

Kessler offers dozens of specific opinions concerning what he alleges to be the Manufacturers' false and misleading marketing statements about prescription opioids, including that they minimized the risks of addiction and abuse and exaggerated the benefits of use. Kessler is particularly critical of the Manufacturers' promotional efforts to increase dosing and to advance the theory of 'pseudoaddiction.'[2] Kessler also proposes corrective measures involving promotion, advertising, and professional education directed to the individuals who received the allegedly false

[2] According to Kessler, "pseudoaddiction" describes "a patient who appears 'looking like a drug addict' but is instead in pain and displaying symptoms of pseudoaddiction, *i.e*., 'misinterpretation of relief-seeking behaviors as drug-seeking behaviors.'" Kessler Report at 62 (Doc. #: 1927-3) (quoting PPLP003877027 at 9; Weissman, D. and J. Haddox. (1989). Opioid pseudoaddiction--an iatrogenic syndrome. Pain. 36(3): 363-66.))

and misleading messaging from the Manufacturers in the first place. *See id*. at 314-320. And, Kessler creates charts and spreadsheets summarizing the information he reviewed, including voluminous sales representative call notes, labeling information, and FDA documentation. *See id*. at Schedules 1-12.

C. Analysis.

Defendants assert Kessler should be excluded from testifying about three general areas and one specific area. They first argue Kessler's report amounts to nothing more than a lengthy factual narrative, including hundreds of pages of one-sided selective quotes from the Manufacturers' documents, followed by his opinions about each Manufacturer. Motion at 10 ((Doc. #: 1927-1). According to Defendants, this type of narrative summary of the evidence usurps the role of lawyers and the jury. *Id*. at 11. Plaintiffs address these criticisms by urging it is common, and acceptable, to allow experts to discuss documents on which they rely in formulating their opinions—particularly when the documents are generated by a party. *See* Opp. at 4-6 (Doc. #: 2195). Plaintiffs emphasize that, as long as the expert is summarizing voluminous records and material or explaining a complicated issue to the jury, and not simply "regurgitating" evidence, narrative testimony is permissible. *See id.* at 7. Plaintiffs also argue that Defendants' concerns should be addressed at trial when Kessler is testifying, and not in a *Daubert* motion. *See id*. at 6-7.

Second, Defendants complain that Kessler offers improper, speculative testimony about the Manufacturers' corporate knowledge, intent, and state of mind. Defs. Mtn. to Excl. Kessler & Perri at 10 ((Doc. #: 1927-1). It is Defendants' position that this testimony is simply "mind reading" and invades the province of the jury. *See id*. at 11-12. Plaintiffs take the position that

Rule 702 only precludes s*peculative* testimony regarding motive, knowledge, and intent and testimony is admissible if based on a proper factual foundation. *See* Opp. at 4-6 (Doc. #: 2195). Plaintiffs also take issue with the examples cited by Defendants, noting that Kessler's statements were solicited by Defendants as "soundbites" and did not accurately reflect Kessler's testimony or opinions. *See id.* at 11-12.

Third, Defendants argue Kessler's opinions concerning whether the Manufacturers violated state and federal law constitute improper legal opinions. Motion at 16-17 (Doc. #: 1927-1). Defendants refer specifically to Kessler's statement that "he will testify to the 'responsibilities' of pharmaceutical companies under the FDCA," which Defendants contend is only a "nominal justification to support his legal conclusions that the manufacturers violated state and federal law." *Id*. at 17 (quoting Kessler Report at 14 (Doc. #: 1927-3)).[3] In response, Plaintiffs assert that courts routinely allow qualified experts to testify about FDA regulations, to opine whether a party complied with FDA regulations, and to describe the duty of care under state law. *See* Pls. Opp. Resp. re Kessler & Perri at 21 (Doc. #: 2195). It is Plaintiffs' position that Kessler is "eminently qualified to testify as to the state law duty of care for drug makers." *Id*. More specifically, Plaintiffs take the position that Kessler's conclusions implicating state tort law is admissible as long as he applies the facts (as he understands them) to the law (as he understands it) and as instructed by the Court. *See id*. at 22.

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[3] Defendants provide three exemplar statements from Kessler's report: (i) Purdue "misbranded OxyContin as a drug that is safer and more effective than it actually is without substantial Evidence." Defs. Mtn. to Excl. Kessler & Perri at 17 ((Doc. #: 1927-3) (quoting Kessler Report at 40, ¶ 99 (Doc. #: 1927-3)); (ii) "Endo's sales force falsely marketed Opana ER as a safer than other opioids." *Id.* (quoting Kessler Report at 131, ¶ 221(Doc. #: 1927-3)); and (iii) "Janssens's marketing of Duragesic broadened its indications beyond the label." *Id*. (quoting Kessler Report at 180, ¶ 307(Doc. #: 1927-3)). These quotes represent only a portion of Kessler's testimony inasmuch as Kessler explains that each statement is based on specific documents produced by the referenced Manufacturer.

Finally, Defendants specifically object to Kessler offering opinions regarding Noramco and Tasmanian Alkaloids, asserting he failed to disclose these opinions in his report and, therefore, they are untimely and should be excluded. *See* Motion at 19-20 ((Doc. #: 1927-1). Plaintiffs respond that Kessler's opinions regarding Noramco and Tasmanian Alkaloids should not be excluded because they were based on documents previously identified by Kessler, these opinions were addressed at his deposition in response to specific questions by Defendants, and Defendants never sought to re-open Kessler's deposition to question him further about these opinions.

The Court is mindful that narrative testimony, legal opinion, and testimony as to another's knowledge, intent or state of mind, is often excluded; and the Court will critically examine any efforts to introduce such testimony. However, Defendants fail to identify the specific opinions or the particular testimony of Kessler they seek to exclude. Rather, Defendants make generic complaints about the *types* of opinions and *categories* of testimony which Kessler should not be permitted to provide. In essence, Defendants are asking the Court to issue an advisory ruling excluding *unspecified*: (i) narrative testimony; (ii) testimony as to knowledge, intent, and state of mind; and (iii) "legal opinions" without detailing the specific opinions or testimony. The Court will not make non-specific rulings on the record before it. In its opinions on the many motions to exclude filed in this case, the Court has explained that standards it will apply. As the multitude of cases cited in the Kessler/Perri Motion and Plaintiffs' Response also make clear, the admissibility of a particular statement or opinion is dependent on the context in which it is offered and the foundation on which it is based. The Court will take these factors and the relevant law into account when ruling at trial on the admissibility of Kessler's testimony, pursuant to its continuing duties to assess the admissibility of expert testimony under the federal rules and *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579 (1993).

Defendants do raise valid concerns and the Court agrees that, in general, no expert will be allowed at trial to offer legal opinions, to opine on whether a Defendant complied with the law, to offer lengthy narrative recitals of facts or of excerpts from documents, or to testify on what was a Defendant's state of mind. But Kessler may testify as to most if not virtually all of his specific opinions without crossing these boundaries. Accordingly, the portion of Defendants' motion pertaining to Kessler's general opinions is denied.[4]

In contrast, the Court grants Defendants' specific objection to Kessler's opinions regarding Noramco and Tasmanian Alkaloids. Kessler's opinions regarding these entities were not disclosed in his lengthy report, so he will not be permitted to offer expert opinions about Noramco and Tasmanian Alkaloids at trial. This ruling, however, does not preclude testimony by Kessler regarding *facts* pertaining to Noramco and Tasmanian Alkaloids, to the extent the facts about which he testifies are supported by documents identified by him in his report and its attachments.

IV. Perri.

A. Credentials and Experience.

Perri received his Bachelor of Science in Pharmacy from Temple University School of Pharmacy in 1981; and his Ph.D., with dual concentrations in pharmacy and marketing, from the

[4] In their Reply, Defendants argue for the first time that Kessler is not qualified to testify about pharmaceutical marketing. Reply at 8. Contrary to Defendants' assertion that this matter was addressed in their motion, the only references to Kessler's marketing expertise were the phrases: (i) "Kessler, similarly, seeks to offer testimony that is beyond his expertise;" and (ii) "Kessler has no educational background in marketing." Motion at 1, 12 (Doc. #: 1927-1). Defendants offered neither briefing nor analysis on this issue and the Court will not reach it here. *See Digital Media Sols., LLC v. S. Univ. of Ohio, LLC*, 2019 WL 1958510, at *1 (N.D. Ohio May 2, 2019); *Ross v. Choice Hotels Int'l, Inc.*, 882 F. Supp. 2d 951 (S.D. Ohio 2012) ("a reply brief is not the proper place to raise an issue for the first time") (citations omitted).

University of South Carolina in 1985. Since 1985, Perri has held academic and administrative positions at the University of Georgia, where he is currently a Professor and Associate Head of the Department of Clinical and Administrative Pharmacy at the College of Pharmacy. *See* Expert Report of Matthew Perri at 1 (Doc. #: 1927-5); *see also id*. at Sched. 1.

Perri has authored two books, *Pharmaceutical Marketing* and *Financial Analysis in Pharmacy Practice*. *Id*. at 2 and Sched. 1. He has also authored a wide array of book chapters, monographs, speeches, and articles, including articles in peer-reviewed journals such as Medical Care and the Journal of Health Communication. *Id*. In addition, Perri has a received numerous grants and has conducted original research related to pharmaceutical marketing and related policy analyses, including work in the area of opioids funded by sources including the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and private foundations. *See* Opp. at 3 (Doc. #: 2195); Perri Report at Sched. 1 (Doc. #: 1927-5).

B. Opinions.

Perri was asked generally by Plaintiffs to address matters pertaining to Defendants' prescription opioid marketing. *See* Perri Report at 5, ¶ 17 (Doc. #: 1927-5).[5] Perri offered seven opinions, including opinions relating to applicable marketing standards, Defendants' failure to adhere to industry standards, and that Defendants' efforts caused the market for prescription

[5] In connection with this general question, he was also asked to answer six specific questions: (i) what is prescription marketing; (ii) what basic standard or rules, if any, should be followed by prescription opioids marketers; (iii) what marketing strategies did Defendants employ with regard to prescription opioids; (iv) how were Defendants' marketing strategies implemented and marketing messages disseminated; (v) what were Defendants' messages; and (vi) what was the result of opioid marketing. *Id.* at 5-6.

opioids to expand. *See id*. at 7-9. Perri describes the methodology he used to formulate his opinions as follows.

> I applied generally accepted principles of marketing, when I evaluated Defendants' internal marketing environment, the marketing mix variables (price, place, product, and promotion), and Defendants' marketing segmentation, targeting, and positioning strategies and tactics. Using this framework, I identified marketing behaviors and assessed the significance of these behaviors.
>
> Case study methods, grounded in marketing principles, were used to systematically assemble and articulate information (data collection, analysis and interpretation) related to Defendants' marketing activities. These methods are used and relied upon by experts in my field. In the present context, this case study is an in-depth, empirical inquiry into Defendants' marketing.
>
> The case study approach is appropriate for this research for several reasons. Defendants' marketing must be examined in a real-world context to understand the practical aspects of it, and case study methods are ideal for this purpose. In addition, the case study methodology is also appropriate for this analysis because in most forms of research control over subjects is required and that is not possible here. Further, an extensive body of literature exists related to pharmaceutical marketing which provides a theoretical basis for explaining the impact of opioid marketing on the medical community. These considerations suggest and validate the use of a case study research methodology. Finally, the case study method is widely accepted and utilized for research in teaching, business and marketing applications, and within the medical community.
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> ***
>
> Guided by marketing principles, the pharmaceutical marketing literature, and the research questions, I formulated propositions that were either supported or negated by the record (documents and testimony) creating data points. These data points were then linked to the study questions, interpreted in the context of both the case and the literature on pharmaceutical marketing.

Perri Report at 4-6 (Doc. #: 1927-5). To support his contention that the case study approach was appropriate for his research, Perri cites several articles. *See id*. at 5. He also references a number of sources to support his contention that the case study method is widely accepted and utilized for research in teaching, business, and marketing and within the medical community. *See id*. at 6.

C. Analysis.

1. Reliability.

In an effort to exclude Perri's opinion that the Manufacturers violated industry marketing standards, Defendants argue that Perri relied on the wrong "industry standard." *See* Defs. Mtn. to Excl. Kessler & Perri at 6-7 (Doc. #: 1927-1). According to Defendants, Perri bases his analysis on "principles of marketing" rather than on "the most significant and controlling industry standard applicable to Pharmaceutical marketing—the FDA's regulation of pharmaceutical labeling and promotion…." *Id*. Defendants contend Perri's "principles of marketing" methodology is not founded on any published or objective standard and is unreliable. *Id.* at 7. Defendants further object to Perri's opinions as unreliable because they are premised on the assumption, provided by Plaintiffs, that *all* of Defendants' marketing was false and misleading. *See id.*

Plaintiffs respond to Defendants' reliability arguments urging that Defendants misunderstand (or misconstrue) Perri's "case study" methodology, improperly describing it as a "principles of marketing methodology." *See* Pls. Opp. Resp. re Kessler & Perri at 13 (Doc. #: 2195). Plaintiffs' assert Perri, and other experts in his field, routinely apply case study methodology. *Id.* Plaintiffs also deny that *all* Perri's opinions are premised on the assumption that Defendants' marketing conduct was unlawful, noting that only Opinion 5—Defendants' marketing failed to adhere to industry standards in their marketing of opioids—is premised on this assumption. Plaintiffs also emphasize this assumption was one of several data points relevant to Opinion 5. *Id*. at 16-18. Plaintiffs argue further that Perri's assumption that all Defendants' marketing conduct was unlawful is merely the basis of a permissible hypothetical question and

Plaintiffs will establish their hypothesis at trial. *See id*. at 18.[6]

The Court finds Defendants have failed to meet their burden to establish Perri's analytical approach is unreliable. As in initial matter, the parties disagree as to the methodology, or at least the name of the methodology, that Perri applies. Defendants describe Perri's approach as "principles of marketing" methodology. Perri refers to it as "case study" methodology. Given that it is Perri's report, the Court accepts his title. However, regardless of which moniker is applied, the Court must address the admissibility of Perri's non-scientific opinions. The Sixth Circuit has made clear that Rule 702 and *Daubert* are to be broadly construed in this context:

> [T]he fact that [an expert's] opinions may not have been subjected to the crucible of peer review, or that their validity has not been confirmed through empirical analysis, does not render them unreliable and inadmissible. In *United States v. Jones*, this court recognized that the four specific factors utilized in *Daubert* may be of limited utility in the context of non-scientific expert testimony. We noted that 'if [the *Daubert*] framework were to be extended to outside the scientific realm, many types of relevant and reliable expert testimony--that derived substantially from practical experience--would be excluded. Such a result truly would turn *Daubert*, a case intended to relax the admissibility requirements for expert scientific evidence, on its head.' Indeed, even the *Berry* court itself recognized that 'the distinction between scientific and nonscientific expert testimony is a critical one[,]' and that *Daubert* is 'only of limited help' in assessing technical or experiential expertise. Consequently, in *Jones* we declined the appellant's invitation to apply the factors outlined in *Daubert* to testimony involving a non-scientific field.

Vinel v. Union Twp., No. 1:16-CV-930, 2018 WL 7080037, *6-7 (S.D. Ohio Apr. 13, 2018) (quoting *First Tenn. Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 334 (6th Cir. 2001) (internal citations omitted)).

This is not to say that nonscientific expert testimony need not pass muster. The expert "must explain how that experience leads to the conclusion reached, why that experience is a

[6] Plaintiffs also address Defendants argument that Perri's opinions based on the same methodology were excluded in *United States v. AseraCare, Inc*., 2014 WL 6879254, at *11-12 (N.D. Ala. Dec. 4, 2014).

sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702, advisory committee note, 2000 amend. The Court must also analyze whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

The Court finds Perri's report sets forth (i) an adequate explanation of his methodology, and (ii) how it is similar to the methodology he uses in his work apart from his role as an expert in this case. Perri iterates numerous widely-accepted principles of marketing and how the Defendants used these principles;[7] this case study methodology is commonly used, and Perri's report refers to sources showing that his methodology was appropriate, widely-accepted, and utilized in his field. Although Defendants complain about Perri's methodology, they do not provide evidence or argument contradicting Perri's support for his methodology.

The case law cited by Defendants is also unhelpful to their position. For example, in *Rose v. Mattrixx Initiatives, Inc.*, 2009 WL 902311, at 15 (W.D. Tenn. Mar. 31, 2009), the court rejected a scientific expert's general causation opinion because it was based solely on three inapplicable case studies, one of which had been previously rejected, and one of which used a small sample size and had never been subject to rigorous scientific assessment. Perri's opinions are quite different in foundation, character and scope. In *Vinel v. Union Twp.*, the court excluded an expert because his three-page report did not provide "enough of a substantive explanation of how [the expert's] experience in the firefighting industry support the key conclusions…." *Vinel*, 2018 WL

[7] For example, Perri opines: (1) it is well-known and established that sales visits targeted at specific doctors (known as "detailing") regarding a given drug can be a very effective tactic to increase the number of prescriptions those doctors write for that drug; and (2) evidence shows Defendants used this principle successfully to increase opioid prescriptions, and the detailing they undertook included supplying doctors with allegedly false information. *See* Report at 29-35 & 76-83.

7080037, *7. Perri's report is hundreds of pages long and provides detailed explanations for his positions.

Furthermore, at this stage of the proceedings, the Court also rejects Defendants' argument that Perri's reliance on the assumption that all of Defendants' marketing was false and misleading renders all of his opinions unreliable. The assumption that all of Defendants' marketing was false and misleading is one of many assumptions that played a role in a portion of Perri's analysis. If this is a faulty assumption, as Defendants allege, they will have the opportunity for "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" to attack Perri's opinions. *Burgett v. Troy–Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Daubert*, 509 U.S. at 596). Neither is it unreasonable for Perri to premise portions of his analysis on assumptions consistent with Plaintiffs' liability theories. That all of Defendants' marketing was false and misleading is one such theory. *See Avery Dennison Corp. v. Four Pillars Enterprise Co.*, 45 Fed. App'x 479, 487 (6th Cir. 2002) ("The 'facts' challenged … here are not scientific facts to be evaluated under *Daubert*, but are rather the central questions of liability in the case, which were properly presented to the jury."); *see also* Order at 13 (Doc. #: 2495) ("[The] assumption that all of Defendants' detailing was unlawful is consistent with Plaintiffs' theory of liability. Defendants are free to challenge that assumption, of course, but the assumption does not cause a problem of fit, nor does it render her overall methodology unreliable. * * * Defendants may well convince a jury it is not true that all of defendants' detailing was fraudulent and tainted by misrepresentations – but [the] central assumption does not render [the expert's] opinion inadmissible.").

And, to the extent Perri's assumption amounts to a hypothetical, "it is proper for a party to pose hypothetical questions to experts." *United States v. McCafferty*, 801 F.Supp. 2d 605, 621

(N.D. Ohio 2011) (citing *Jackson v. A–C Prod. Liab. Trust*, 622 F.Supp. 2d 641, 646 (N.D. Ohio 2009)). However, hypothetical questions should be "an accurate summation of the evidence already presented in the record and can neither add nor distract from that evidence." *Myers v. Weinberger*, 514 F.2d. 293, 294 (6th Cir. 1975) (reversing judgment for defendant in a disability case where defendant failed to present evidence, other than in the form of a hypothetical question, that plaintiff was able to perform another job). At trial, prior to the introduction of Perri's testimony dependent on this assumption, the Court will require Plaintiffs to establish that there is sufficient evidentiary support in the record for Perri's testimony.

2. Relevance/Fit.

Defendants complain that Perri's opinions should be excluded because they do not "fit' the facts and law of the case and will not be helpful to the trier of fact. *See* Motion at 8-9 (Doc. #: 1927-1). Defendants take issue with Perri's conclusions that: (i) the Defendants' marketing improperly expanded the indication for opioid use from 'more than a few days' to 'chronic use;' and (ii) Defendants' labeling omitted 'side effects associated with long term use.' *Id*. at 8. According to Defendants, these conclusions are a "naked attack on the FDA-approved indication of certain opioid medications for daily, around-the-clock, long-term opioid treatment" and, as such, address an 'impermissible position' rendering them irrelevant and inadmissible. *Id*. (emphasis omitted). Defendants also assert these two conclusions contradict Plaintiffs' own theory of the case, set forth in their opposition to Defendants' Motion to Dismiss, where Plaintiffs represented that their claims were *not* premised on "allegations that Defendants falsely claimed their medications were 'safe and effective for the long term treatment of chronic non-cancer pain.'"

Id. at 9 (quoting November 5, 2018 Report and Recommendation of Magistrate Judge Ruiz at 49 (Doc. #: 1025); *see also* Doc. #: 654.

Plaintiffs respond that Perri's statement constitutes neither an opinion about nor an indictment of the FDA. Instead, Plaintiffs contend Perri's comment is nothing more than a single sentence from his 155-page report addressing Defendants' marketing themes, not the propriety of any FDA-approved labeling. *See* Opp. at 20 (Doc. #: 2195). As further support, Plaintiffs note that Perri's statement corresponds to the facts of the case and Plaintiffs' case theories regarding Defendants' marketing themes. *See id*. at 20.

The Court agrees with Plaintiffs. The specific comments identified by Defendants, like the majority of Perri's report, are directed to Defendants' marketing activities. Whether these types of comments on marketing contradict FDA requirements and are, therefore, preempted was previously addressed and rejected. *See* Report and Recommendation at 49 (Doc. #: 1025); *see also* forthcoming order regarding motions for summary judgment on preemption grounds. This is still the case and the Court does not perceive a contradiction between the position Plaintiffs took in their response to Defendants' motions to dismiss and their position now.

The "fit" requirement set forth in *Daubert* seeks to ensure that a jury is presented with expert evidence only when that evidence is demonstrably germane to the facts of the case. At its core, the relevance standard is "a liberal one" premised on Federal Rule of Evidence 401. *Daubert*, 509 U.S. at 587 ("Relevant evidence is defined as that which has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.") (internal quotation marks omitted). Only if expert testimony does not relate to any issue in the case should it be excluded. *See United States v. Bonds*, 12 F.3d 540,555 (6th Cir. 1993) (expert testimony that does not relate to any issue in the

case is not relevant and, therefore, not helpful). Plaintiffs have explained how Perri's statements relate to relevant issues in the case and the Court concludes they will be helpful to the jury.

3. Narrative Testimony and Testimony as to Intent, State of Mind, and Knowledge.

Finally, Defendants seek to exclude portions of Perri's testimony, arguing it violates Rule 702 and *Daubert* because it contains a lengthy reiteration of the marketing strategy for opioids that is nothing more than selective excerpting of Defendants' documents in a narrative format. Defs. Mtn. to Excl. Kessler & Perri at 10 ((Doc. #: 1927-3). Defendants also complain Perri fails to differentiate between the Defendants, their products, their marketing, and their materials, transforming them into a "monolithic entity." *Id*. In addition, Defendants seek to exclude Perri's testimony to the extent he seeks to offer opinions about Defendants' knowledge, intent, or state of mind. *See id*. at 13-15.

As discussed above with regard to Defendants' criticism of Kessler's report, Defendants fail to identify the specific opinions or the particular testimony of Perri they seek to exclude. And, as the Court noted with regard to Kessler's testimony, the Court will critically review any testimony before allowing it to be presented to the trier of fact, as is required pursuant to its continuing role as gatekeeper under the Federal Rules of Evidence and *Daubert*.

V. Conclusion.

For the foregoing reasons, Defendants' Motion to Exclude the Testimony of David A. Kessler, M.D. and Matthew Perri, III, BS Pharm, Ph.D., RPh is **GRANTED IN PART AND DENIED IN PART.**

IT IS SO ORDERED.

/s/ Dan Aaron Polster ***September 3, 2019***
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE